

Food and Drug Administration, HHS

§ 172.5

Subpart H—Other Specific Usage Additives

- 172.710 Adjuvants for pesticide use dilutions.
- 172.712 1,3-Butylene glycol.
- 172.715 Calcium lignosulfonate.
- 172.720 Calcium lactobionate.
- 172.723 Epoxidized soybean oil.
- 172.725 Gibberellic acid and its potassium salt.
- 172.730 Potassium bromate.
- 172.735 Glycerol ester of wood rosin.
- 172.755 Stearyl monoglyceridyl citrate.
- 172.765 Succistearin (stearoyl propylene glycol hydrogen succinate).
- 172.770 Ethylene oxide polymer.
- 172.775 Methacrylic acid-divinylbenzene copolymer.

Subpart I—Multipurpose Additives

- 172.800 Acesulfame potassium.
- 172.802 Acetone peroxides.
- 172.804 Aspartame.
- 172.806 Azodicarbonamide.
- 172.808 Copolymer condensates of ethylene oxide and propylene oxide.
- 172.809 Curdlan.
- 172.810 Dioctyl sodium sulfosuccinate.
- 172.811 Glyceryl tristearate.
- 172.812 Glycine.
- 172.814 Hydroxylated lecithin.
- 172.816 Methyl glucoside-coconut oil ester.
- 172.818 Oxystearin.
- 172.820 Polyethylene glycol (mean molecular weight 200-9,500).
- 172.822 Sodium lauryl sulfate.
- 172.824 Sodium mono- and dimethyl naphthalene sulfonates.
- 172.826 Sodium stearyl fumarate.
- 172.828 Acetylated monoglycerides.
- 172.830 Succinylated monoglycerides.
- 172.832 Monoglyceride citrate.
- 172.834 Ethoxylated mono- and diglycerides.
- 172.836 Polysorbate 60.
- 172.838 Polysorbate 65.
- 172.840 Polysorbate 80.
- 172.841 Polydextrose.
- 172.842 Sorbitan monostearate.
- 172.844 Calcium stearoyl-2-lactylate.
- 172.846 Sodium stearoyl-2-lactylate.
- 172.848 Lactylic esters of fatty acids.
- 172.850 Lactylated fatty acid esters of glycerol and propylene glycol.
- 172.852 Glyceryl-lacto esters of fatty acids.
- 172.854 Polyglycerol esters of fatty acids.
- 172.856 Propylene glycol mono- and diesters of fats and fatty acids.
- 172.858 Propylene glycol alginate.
- 172.859 Sucrose fatty acid esters.
- 172.860 Fatty acids.
- 172.861 Cocoa butter substitute from coconut oil, palm kernel oil, or both oils.
- 172.862 Oleic acid derived from tall oil fatty acids.
- 172.863 Salts of fatty acids.
- 172.864 Synthetic fatty alcohols.

- 172.866 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.
- 172.867 Olestra.
- 172.868 Ethyl cellulose.
- 172.870 Hydroxypropyl cellulose.
- 172.872 Methyl ethyl cellulose.
- 172.874 Hydroxypropyl methylcellulose.
- 172.876 Castor oil.
- 172.878 White mineral oil.
- 172.880 Petrolatum.
- 172.882 Synthetic isoparaffinic petroleum hydrocarbons.
- 172.884 Odorless light petroleum hydrocarbons.
- 172.886 Petroleum wax.
- 172.888 Synthetic petroleum wax.
- 172.890 Rice bran wax.
- 172.892 Food starch-modified.
- 172.894 Modified cottonseed products intended for human consumption.
- 172.896 Dried yeasts.
- 172.898 Bakers yeast glycan.

AUTHORITY: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

SOURCE: 42 FR 14491, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 172 appear at 61 FR 14482, Apr. 2, 1996.

Subpart A—General Provisions

§ 172.5 General provisions for direct food additives.

(a) Regulations prescribing conditions under which food additive substances may be safely used predicate usage under conditions of good manufacturing practice. For the purposes of this part, good manufacturing practice shall be defined to include the following restrictions.

(1) The quantity of the substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect in food.

(2) Any substance intended for use in or on food is of appropriate food grade and is prepared and handled as a food ingredient.

(b) The existence of a regulation prescribing safe conditions of use for a food additive shall not be construed to relieve the use of the substance from compliance with any other provision of the Act.

(c) The existence of any regulation prescribing safe conditions of use for a nutrient substance does not constitute a finding that the substance is useful

or required as a supplement to the diet of humans.

Subpart B—Food Preservatives

§ 172.105 Anoxomer.

Anoxomer as identified in this section may be safely used in accordance with the following conditions:

(a) Anoxomer is 1,4-benzenediol, 2-(1,1-dimethylethyl)-polymer with diethenylbenzene, 4-(1,1-dimethylethyl)phenol, 4-methoxyphenol, 4,4'-(1-methylethylidene)bis(phenol) and 4-methylphenol (CAS Reg. No. 60837-57-2) prepared by condensation polymerization of divinylbenzene (*m*- and *p*-) with *tert*-butylhydroquinone, *tert*-butylphenol, hydroxyanisole, *p*-cresol and 4,4'-isopropylidenediphenol.

(b) The polymeric antioxidant meets the following specifications:

(1) Polymer, not less than 98.0 percent as determined by an ultraviolet method entitled "Ultraviolet Assay," 1982, which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(2) Molecular weight: Total monomers, dimers and trimers below 500 not more than 1 percent as determined by a method entitled "Low Molecular Weight Anoxomer Analysis," 1982, which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(3) Phenol content: Not less than 3.2 milliequivalent/gram and not more than 3.8 milliequivalent/gram as determined by a method entitled "Total Phenols," 1982, which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal

Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(4) Heavy metals as lead (as Pb), not more than 10 parts per million. Arsenic (as As), not more than 3 parts per million. Mercury (as Hg), not more than 1 part per million.

(c) Anoxomer may be safely used as an antioxidant in food at a level of not more than 5,000 parts per million based on fat and oil content of the food.

[48 FR 18798, Apr. 26, 1983, as amended at 54 FR 24896, June 12, 1989]

§ 172.110 BHA.

The food additive BHA (butylated hydroxyanisole) alone or in combination with other antioxidants permitted in food for human consumption in this subpart B may be safely used in or on specified foods, as follows:

(a) The BHA meets the following specification:

Assay (total BHA), 98.5 percent minimum. Melting point 48 °C minimum.

(b) The BHA is used alone or in combination with BHT, as an antioxidant in foods, as follows:

Food	Limitations (total BHA and BHT) parts per million
Dehydrated potato shreds	50
Active dry yeast	11,000
Beverages and desserts prepared from dry mixes	12
Dry breakfast cereals	50
Dry diced glazed fruit	132
Dry mixes for beverages and desserts	190
Emulsion stabilizers for shortenings	200
Potato flakes	50
Potato granules	10
Sweet potato flakes	50

¹ BHA only.

(c) To assure safe use of the additive:

(1) The label of any market package of the additive shall bear, in addition to the other information required by the Act, the name of the additive.

(2) When the additive is marketed in a suitable carrier, in addition to meeting the requirement of paragraph (c)(1) of this section, the label shall declare the percentage of the additive in the mixture.

(3) The label or labeling of dry mixes for beverages and desserts shall bear adequate directions for use to provide that beverages and desserts prepared